Nos. 23-11535-A, 23-11536-A, 23-11537-A, 23-11538-A, 23-11539-A

UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

IN RE: DEEPWATER HORIZON BELO CASES

BELO PLAINTIFFS, LESTER JENKINS, DWIGHT SIPLES, KENNETH DAVENPORT, and MICHAEL MOULDER,

Plaintiffs/Appellants,

v.

BP EXPLORATION & PRODUCTION, INC. and BP AMERICA PRODUCTION COMPANY,

Defendants/Appellees.

Appeal from the United States District Court for the Northern District of Florida
Case Nos. 3:19-cv-00963, 5:18-00245, 5:19-cv-00012,
5:19-cv-00260, 5:19-cv-00310

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

In compliance with 11th Circuit Rule 26.1-1, the undersigned certifies that the following is a complete list of all trial judges, attorneys, persons, associations of persons, firms, partnerships, or corporations that have an interest in the outcome of this particular case or appeal, and includes subsidiaries, conglomerates, affiliates and parent corporations, including any publicly held company that owns 10% or more of the party's stock, and other identifiable legal entities related to a party.

Allen, Harley D., Plaintiff in related Back End Litigation Option ("BELO") case that has been dismissed with prejudice in a separate order that resulted from the order on appeal.

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Barkley, Shon, Plaintiff in related BELO case that has been dismissed with prejudice in a separate order that resulted from the order on appeal.

Barsanti, Vanessa A., trial counsel for Appellees/Defendants BP America Production Company and BP Exploration and Production, Inc.

Beard, Jeffrey, Plaintiff in related BELO case that has been dismissed with prejudice in a separate order that resulted from the order on appeal.

Blount, Larry E., Plaintiff in related BELO case that has been dismissed with prejudice in a separate order that resulted from the order on appeal.

Boigris, Dylan B.A., counsel for Appellants/Plaintiffs Kenneth Davenport, Lester Jenkins, Michael Moulder, and Dwight Siples, and for other Plaintiffs listed herein whose related BELO cases have been dismissed or partially dismissed in a separate order that resulted from the order on appeal.[1]

Bourn, Stefan G., trial counsel for Appellees/Defendants BP America Production Company and BP Exploration and Production, Inc.

Bowdry, Fabrice, Plaintiff in related BELO case that has been dismissed with prejudice in a separate order that resulted from the order on appeal.

BP America Production Company, Appellee/Defendant. BP America Production Company is not publicly traded. BP America Production Company is an indirect wholly-owned subsidiary of BP p.l.c., a company incorporated under the laws of England and Wales.

BP Exploration and Production, Inc., Appellee/Defendant. BP Exploration & Production Inc. is not publicly traded. BP Exploration & Production Inc. is an

[1] Appellants/Plaintiffs Kenneth Davenport and Michael Moulder have filed motions to be dismissed from this consolidated appeal and to dismiss their individual appeals under Case Nos. 23-11536-A and 23-11537-A.

indirect wholly-owned subsidiary of BP p.l.c., a company incorporated under the laws of England and Wales.

BP p.l.c. (LON: BP; FWB: BPE; NYSE: BP), related to Appellees/Defendants BP America Production Company and BP Exploration & Production Inc. The primary market for BP p.l.c.'s ordinary shares is the London Stock Exchange (LSE). BP p.l.c.'s ordinary shares are a constituent element of the Financial Times Stock Exchange 100 Index. BP p.l.c.'s ordinary shares are also traded on the Frankfurt Stock Exchange in Germany. In the United States, BP p.l.c.'s securities are traded on the New York Stock Exchange (NYSE) in the form of American Depository Shares.

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Brown, Christopher W., Plaintiff in related BELO case that has been dismissed with prejudice in a separate order that resulted from the order on appeal.

Brown, Timothy Jr., Plaintiff in related BELO case that has been partially dismissed with prejudice in a separate order that resulted from the order on appeal, but otherwise remains pending.

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Cannon, Hope T., United States Magistrate Judge in underlying matter, who issued the Order and Report and Recommendation adopted by the order on appeal.

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Cook, Shaunette, Plaintiff in related BELO case that has been partially dismissed with prejudice in a separate order that resulted from the order on appeal, but otherwise remains pending.

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Crump, Richard M., trial counsel for Appellees/Defendants BP America Production Company and BP Exploration and Production, Inc.

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Fountain, Larry, Plaintiff in related BELO case that has been dismissed with prejudice in a separate order that resulted from the order on appeal.

Gerkin, Travis R., Plaintiff in related BELO case that has been dismissed with prejudice in a separate order that resulted from the order on appeal.

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Jones, Gary R., United States Magistrate Judge formerly assigned to underlying matter.

Kennedy, Jessica M., trial counsel for Appellees/Defendants BP America Production Company and BP Exploration and Production, Inc.

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Kirkland, Luther H., Plaintiff in related BELO case that has been partially dismissed with prejudice in a separate order that resulted from the order on appeal, but otherwise remains pending.

Larey, Jason M., trial counsel for Appellants/Plaintiffs Kenneth Davenport, Lester Jenkins, Michael Moulder, and Dwight Siples, and for other Plaintiffs listed herein whose related BELO cases have been dismissed or partially dismissed in a separate order that resulted from the order on appeal.

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Mancini, Sara M., former trial counsel for Appellants/Plaintiffs Kenneth Davenport, Lester Jenkins, Michael Moulder, and Dwight Siples.

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STATEMENT REGARDING ORAL ARGUMENT

Plaintiffs / Appellants (hereafter "Plaintiffs") request oral argument, which they believe will assist the Court in deciding this consolidated appeal. This appeal raises a multitude of scientific, legal, and factual issues concerning the admissibility of expert testimony offered to show general causation in Plaintiffs' toxic tort cases. Given the number and complexity of issues raised by Plaintiffs, the Court will likely have many questions for both sides at oral argument.

Some of those issues have great importance beyond this case, not only for dozens of other lawsuits arising out of the BP Deepwater Horizon oil spill, but also for every toxic tort case in which general causation is disputed. Plaintiffs contend that district court decisions in this case and in other cases have misconstrued this Court's precedents concerning the factual basis and methodology required to support an expert opinion on general causation. The Court should examine those issues in depth and clarify its precedents in this area, and oral argument would assist the Court in that endeavor.

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STATEMENT REGARDING JURISDICTION

The district court had federal admiralty and maritime jurisdiction over Plaintiffs' actions pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1333, and 46 U.S.C. § 30101(a),(b), because Plaintiffs sought damages for personal injuries consummated on land that were caused by a vessel on navigable waters, the BP Deepwater Horizon mobile offshore drilling rig. 5:19-cv-00260, Doc.1 at 2-6; 5:19-cv-00310, Doc.1 at 2-6; 5:18-cv-00245, Doc.1 at 2-6; 5:19-cv-00012, Doc.l at 2-6 and Doc.40 at 207.[2] In addition, or alternatively, the district court had diversity jurisdiction under 28 U.S.C. § 1332 because at the time of filing suit, each Plaintiff was a citizen of Florida, Defendants / Appellees BP Exploration & Production Inc. and BP America Production Company (hereafter "BP") were both citizens of Delaware and Texas, and the amount in controversy in each suit exceeded $75,000 exclusive of interest and costs. 5:19-cv-00260, Doc.1 at 1-2; 5:19-cv-00310, Doc.1 at 1-2; 5:18-cv-00245, Doc.1 at 1-2; 5:19-cv-00012, Doc.l at 1-2.

This Court has appellate jurisdiction pursuant to 28 U.S.C. §1291, as this appeal is taken from a final order of summary judgment entered against all Plaintiffs jointly and final judgments entered against each Plaintiff individually, each of which resolved all claims between the parties. The district court entered its final summary

[2] Herein, citations to the records from Plaintiffs' individual cases will provide the district court case number; the document number listed in the ECF header, preceded by "Doc."; and the page number(s) listed in the ECF header.

judgment order on March 30, 2023. Doc.591 at 13.[3] The clerk of the district court entered a final judgment in each Plaintiff's individual case on the same date. 5:19-cv-00260, Doc.64; 5:19-cv-00310, Doc.65; 5:18-cv-00245, Doc.72; 5:19-cv-00012, Doc.102. Plaintiffs timely filed a joint notice of appeal on April 28, 2023. Doc.608.

[3] Herein, record citations that omit the district court case number refer to the district court's "master docket" for BELO cases, Case No. 3:19-cv-00963, from which Eleventh Circuit Case No. 23-11535-A originated.

STATEMENT OF THE ISSUES

I. Whether the district court erred in requiring Plaintiffs' general causation experts to identify a threshold harmful dose.

II. Whether the district court abused its discretion in finding that Drs. Freeman and Solomon did not reliably consider the Rusiecki (2022) study.

III. Whether the district court erred in requiring Plaintiffs' experts to analyze general causation for specific chemicals contained in crude oil or dispersants.

IV & V. Whether the district court abused its discretion in excluding Dr. Freeman's and Dr. Solomon's opinions regarding general causation of chronic sinusitis.

VI. Whether the district court erred in granting summary judgment against Plaintiffs Jenkins and Siples.

STATEMENT OF THE CASE

A. Nature of appeal, course of proceedings below, and relevant facts.

This is an appeal from an order that excludes expert testimony offered by Plaintiffs to establish general causation in their toxic tort cases and enters summary judgment based on the exclusion of that evidence. Doc.570. Plaintiffs Davenport and Moulder have filed motions to dismiss themselves from this appeal, leaving Plaintiffs Jenkins and Siples as the sole Appellants.

The oil spill. Plaintiffs were cleanup workers in the response to the BP Deepwater Horizon ("DWH") oil spill. Doc.570 at 1. The DWH disaster released 200 million gallons of crude oil into the Gulf of Mexico and contaminated 68,000 square miles of shoreline. Doc.469-1 at 5. The response to the oil spill employed 90,000 workers and included the release of two million gallons of dispersants to break up the oil. Doc.97 at 6; Doc.469-1 at 5.

The litigation. Thousands of claims were filed against BP and consolidated into multi-district litigation, which was partly resolved by a class settlement agreement. Doc.45-1; Doc.570 at 5; Doc.591 at 1, n.2. Class members who were diagnosed with a qualifying health condition after April 16, 2012, may bring a Backend Litigation Option ("BELO") lawsuit. Doc.570 at 5; Doc.45-1 at 12, 60-63. In a BELO suit, the plaintiff must prove that his or her health condition was legally caused by exposure to oil, other substances released by the spill, or dispersants and

decontaminants used in the response effort. Doc.45-1 at 70. BP may not dispute that the plaintiff was exposed to those substances, but it may contest the level or duration of the plaintiff's exposure and whether it caused the plaintiff's illness. *Id.* at 69-71.

Hundreds of BELO cases were transferred to the Northern District of Florida. Doc.570 at 5. The district court adopted a bifurcated process where a handful of BELO cases would be selected as test cases to determine general causation (whether exposure to crude oil, dispersants, or other substances *could* cause a given health condition) before proceeding to litigation of specific causation (whether such an exposure *did* cause that health condition in each individual plaintiff). Doc.342 at 2-4; Doc.591 at 3. The district court's ruling on general causation would be binding on all BELO plaintiffs who had the same health conditions and were represented by the same counsel as the test-case plaintiffs. Doc.342 at 5-6.

Plaintiffs' health conditions. Plaintiffs were selected as bellwethers to determine general causation of sinus and ocular conditions. Plaintiffs Jenkins and Siples allege that they developed chronic sinusitis caused by their exposures to oil, dispersants, and other harmful chemicals from performing cleanup work in Florida. 5:19-cv-00260, Doc.27 at 7-8; 5:18-cv-00310, Doc.1 at 5-6. Plaintiffs Davenport and Moulder allege that they developed chronic ocular conditions, but they have decided not to pursue this appeal, so only chronic sinusitis remains at issue.

The record variously refers to chronic sinusitis, which is chronic inflammation of the sinuses, and chronic *rhino*sinusitis, which is chronic inflammation of the sinuses and nasal passages. Doc.469-7 at 47; Doc.514-3 at 4, ¶11. The two terms can be used interchangeably. Doc.466-3 at 148; Doc.469-7 at 47. This brief uses "chronic sinusitis" for consistency.

Plaintiffs' general causation experts. Plaintiffs disclosed several expert witnesses but only two of them, Michael Freeman, M.D., Ph.D., and Gina Solomon, M.D., MPH, offered opinions on general causation of chronic sinusitis. Therefore, "Plaintiffs' experts" refers to Dr. Freeman and Dr. Solomon unless the context indicates otherwise.

Dr. Freeman is a consultant in forensic medicine and forensic epidemiology and a member of the Faculty of Forensic and Legal Medicine of the Royal College of Physicians (UK). Doc.469-1 at 3. He is also a tenured Associate Professor of Forensic Medicine and Epidemiology at Maastricht University, and a joint Clinical Professor of Psychiatry and Public Health and Preventative Medicine at Oregon Health and Science University School of Medicine, where he has taught courses in forensic medicine, forensic epidemiology, and injury epidemiology for over twenty years. *Id.* Dr. Freeman's academic degrees include a Doctor of Medicine (M.D.), a Ph.D. in public health / epidemiology, a Master of Public Health in epidemiology and biostatistics, and a master's degree in forensic medical sciences. *Id.* Dr. Freeman

has served as an associate editor or editorial board member of fifteen peer-reviewed scientific journals and has published approximately 230 scientific papers, abstracts, book chapters, and books, including a textbook and more than two dozen peer-reviewed papers and conference abstracts about methods for investigating general and specific causation. Doc.512-1 at 3.

Dr. Solomon is a medical doctor who is employed as a Principal Investigator at the Public Health Institute and a clinical professor at the University of California San Francisco. Doc.466-1 at 3-4, 6. She is board certified in internal medicine and occupational and environmental medicine, and has broad expertise in toxicology, epidemiology, statistics, and risk assessment. *Id.* at 3-4. Dr. Solomon has an M.D. and a master's degree in public health, and she completed post-graduate fellowship in occupational and environmental medicine. *Id.* at 3-4. From 2008 to 2012, Dr. Solomon was the Director of the residency program in occupational and environmental medicine at UCSF, where she still teaches classes in environmental health, toxicology, and risk communication. *Id.* at 4. Dr. Solomon has served as the Deputy Secretary for Science and Health at the California Environmental Protection Agency, where she advised the Secretary on all issues related to toxic chemicals and health. *Id.* She has also served on multiple boards and committees of the National Academy of Sciences and on scientific panels for various agencies, and as a peer reviewer for many well-regarded scientific journals. *Id.* at 5-6. Dr. Solomon has

published over ninety peer-reviewed papers, reports, abstracts, and book chapters. Doc.514-3 at 1.

Expert discovery. Dr. Freeman authored one report on general causation of chronic sinusitis and one on general causation of ocular conditions. Docs.469-1, 469-2. Because only chronic sinusitis remains at issue, "Dr. Freeman's report" shall refer to his chronic sinusitis report. Doc.469-1.

Dr. Solomon wrote separate reports for Mr. Jenkins and Mr. Siples, addressing both general and specific causation. Docs.466-1, 466-2. They are identical regarding general causation, so we will only cite the report for Mr. Jenkins and refer to it as "Dr. Solomon's report."

Although both experts considered a wide range of scientific evidence, they primarily relied on epidemiological studies of the health effects of exposure to oil, dispersants, and other substances among DWH response workers. Doc.469-1 at 14-21; Doc.466-1 at 15-17. Arguably the most important of these studies is Rusiecki (2022) (also referred to as Rusiecki (2021)), which found that DWH response workers who inhaled crude oil fumes had a statistically significant increased risk of chronic sinusitis. Doc.469-1 at 20-21; Doc.466-1 at 16-17; Doc.543-1. Other studies cited in Dr. Freeman's and Dr. Solomons' reports showed that exposure to oil or dispersants was associated with increased respiratory symptoms among DWH response workers. Doc.469-1 at 14-20; Doc.466-1 at 15.

Dr. Freeman and Dr. Solomon also considered a set of criteria known as the Bradford Hill guidelines (also called "viewpoints" or "factors"), which were proposed in 1965 by Sir Austin Bradford Hill. *See* Austin Bradford Hill, *The Environment and Disease: Association or Causation?*, 58 Proc. Royal Soc'y Med. 295 (1965);[4] Federal Judicial Center, *Reference Manual on Scientific Evidence* 600 (3d ed. 2011) ("Reference Manual"). These guidelines are considered by experts to reach an informed judgment of whether an association between a suspected cause and an adverse health effect—like the one shown by Rusiecki (2022)—is a cause-effect relationship. Reference Manual at 597-99. Sir Hill's article listed nine "viewpoints": *Strength* (of the association), *Consistency*, *Specificity*, *Temporality*, *Biological Gradient*, *Plausibility*, *Coherence*, *Experiment*, and *Analogy*. Hill, *supra* at 295-99; Doc.469-1 at 10-12; Doc.466-1 at 8.

Dr. Freeman and Dr. Solomon each evaluated how the Bradford Hill guidelines apply to the scientific evidence they considered and concluded that exposure to chemicals or substances associated with the DWH spill can cause chronic sinusitis. Doc.469-1 at 22-24; Doc.466-1 at 3, 9, 18.

After Plaintiffs' experts submitted their reports, BP's experts submitted theirs. Doc.466-6 at 127-251, Doc.466-7 at 7-154, Doc.466-8 at 5-87. Two of BP's experts,

[4] Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1898525/pdf/procrsmed00196-0010.pdf.

Dr. Alexander and Dr. Cox, criticized the epidemiological studies that Dr. Freeman and Dr. Solomon relied upon, claiming they had inconsistent results and limitations that rendered them unreliable; criticized Dr. Freeman's and Dr. Solomon's methodologies; and disagreed that DWH-related exposures can cause chronic sinusitis. Doc.469-5 at 151-52, 155-58, 167-68, 169-76; Doc.466-7 at 69, 74-75, 80, 93-105.

BP took Dr. Freeman's and Dr. Solomon's depositions. Doc.469-3; Doc.466-3. Among other topics, they addressed various study limitations raised by BP's counsel and explained why they did not undermine their analyses or were not truly limitations. *E.g.*, Doc.469-3 at 43(164), 49-50(185-91), 78-84(204-28), 88-92(244-60);[5] Doc.466-3 at 31-32, 146-52, 157-58, 160-62, 167-76.

Daubert and summary judgment proceedings. BP filed motions to exclude Dr. Freeman's and Dr. Solomon's general causation opinions as unreliable and unhelpful under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Doc.469, 466. BP did not challenge either expert's qualifications. *Id.* BP also filed a motion for summary judgment arguing that Plaintiffs had no admissible expert testimony to establish general causation. Doc.470.

[5] Citations to Dr. Freeman's deposition include the original page numbers in parentheses.

Plaintiffs filed responses to BP's motions to exclude Dr. Freeman and Dr. Solomon, supported with declarations from each expert responding to BP's and its experts' criticisms of Dr. Freeman's and Dr. Solomon's methodologies and the studies they relied upon. Docs.512, 512-1, 514, 514-3. Plaintiffs also responded to BP's motion for summary judgment. Doc.502.

Dr. Freeman wrote a supplemental report, which was attached to his declaration. Doc.512-1 at 16-29. The district court struck Dr. Freeman's supplemental report and the portions of his declaration that referred to it. Doc.570 at 70-71, Doc.591 at 10-12. This brief only cites the portions of Dr. Freeman's declaration that were not struck.

BP filed a reply in support of its motion to exclude Dr. Solomon, along with declarations from Dr. Alexander and Dr. Cox responding to Dr. Solomon's declaration. Docs.543, 543-2, 543-3. Plaintiffs filed a sur-reply, supported with a supplemental declaration of Dr. Solomon further responding to BP's and its experts' arguments. Docs.556, 556-1. BP filed a motion to strike Dr. Solomon's supplemental declaration, which was denied. Doc.561; Doc.570 at 22, n.15.

After oral argument (Doc.619), Magistrate Judge Hope Cannon issued an Order and Report and Recommendation ("R&R") recommending that BP's *Daubert* motions and motion for summary judgment be granted. Doc.570 at 77-79. The R&R excluded Plaintiffs' general causation experts because they did not identify a

threshold harmful dose or identify which specific chemicals contained in crude oil or dispersants could cause Plaintiffs' health conditions. *Id.* at 3-4, 15-20. It also found that Dr. Freeman and Dr. Solomon did not reliably analyze the studies they had relied upon or reliably apply the Bradford Hill guidelines. *Id.* at 25-33, 55-66. Plaintiffs timely filed objections which argued that each of those rulings and findings were erroneous. Doc.577-1 at 1-2, 7-12, 20-24, 30-49, 64-65. The district court overruled Plaintiffs' objections, adopted the R&R, and directed that judgment be entered for BP. Doc.591. Plaintiffs timely appealed. Doc.608.

The district court subsequently dismissed eighteen other BELO cases based on its general causation ruling. Doc.598. The plaintiffs in those cases filed a separate appeal, *Allen v. BP Exploration & Production, Inc.*, Eleventh Circuit No. 23-11707, which is stayed pending the resolution of this appeal.

B. Standards of review.

A district court's ruling on the admissibility of expert testimony is reviewed for an abuse of discretion. *Seamon v. Remington Arms Co., LLC*, 813 F.3d 983, 987 (11th Cir. 2016). The Court defers to the district court's ruling unless it is manifestly erroneous, and will reverse "only if the district court applies an incorrect legal standard, follows improper procedures in making the determination, or makes findings of fact that are clearly erroneous." *Id.* (cleaned up). A district court may also abuse its discretion "when it sets the *Daubert* 'admissibility bar [] too high.'"

Moore v. Intuitive Surgical, Inc., 995 F.3d 839, 854 (11th Cir. 2021) (quoting *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1321 (11th Cir. 1999)).

An order granting summary judgment is reviewed *de novo*. *Seamon*, 813 F.3d at 987. Summary judgment is appropriate if there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a).

SUMMARY OF THE ARGUMENT

I. The district court erred in requiring Plaintiffs' experts to identify a threshold dose of exposure that could cause Plaintiffs' illnesses. General causation only concerns whether exposure to an agent can cause a disease—not the lowest dose that can cause it, which is only relevant to specific causation. The epidemiology-based methodology followed by Plaintiffs' experts does not require a threshold dose to be determined when analyzing general causation, and this Court's precedents do not require an expert to identify a threshold dose when applying that methodology.

II. The R&R abused its discretion in rejecting Dr. Freeman's and Dr. Solomon's reliance on Rusiecki (2022) to support their general causation opinions. Dr. Freeman and Dr. Solomon gave reasonable, scientifically grounded explanations for why Rusiecki (2022)'s findings were not internally inconsistent, as BP's experts claimed, and why other aspects of the study did not undermine their opinions.

III. The district court erred in requiring Plaintiffs to establish general causation for specific chemical components of crude oil or dispersants. Plaintiffs were only required to prove that their conditions were caused by exposure to crude oil, dispersants, or other substances, not chemicals within those substances, and an expert may reliably analyze general causation for mixtures such as crude oil and dispersants.

IV. & V. The district court abused its discretion in excluding Dr. Freeman's and Dr. Solomon's general causation opinions. Both experts reliably analyzed the epidemiology studies and other scientific information they considered, and both reliably applied the Bradford Hill guidelines in reaching their opinions. The R&R's findings to the contrary are clearly erroneous, misconstrue the Bradford Hill guidelines, and improperly review the correctness of the experts' conclusions instead of the reliability of their methodologies.

VI. Because the district court erred in excluding Dr. Freeman's and Dr. Solomon's testimony, it also erred in granting summary judgment against Plaintiffs Jenkins and Siples.

ARGUMENT

I. THE DISTRICT COURT ERRED IN REQUIRING PLAINTIFFS' EXPERTS TO IDENTIFY A THRESHOLD DOSE.

One reason why the district court excluded Plaintiffs' general causation experts is they did not identify a minimum exposure level that could cause Plaintiffs'

diseases—i.e., a threshold dose. Doc.570 at 15-20, 22-24, 55; Doc.591 at 7-9. This was error because: (1) a threshold dose is only relevant to *specific* causation, (2) no principle of epidemiology requires a general causation analysis to include a threshold dose; and (3) this Court's precedents do not require an expert to identify a threshold dose when using the epidemiological evidence methodology for investigating general causation.

A. *Daubert* standards.

Under *Daubert* and Rule 702, expert testimony is admissible if (1) the expert is sufficiently qualified, (2) the expert's methodology is reliable, and (3) the expert's testimony will help the trier of fact determine a fact in issue. *City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 562 (11th Cir. 1998). Here, only the reliability and helpfulness requirements are at issue.

"When evaluating the reliability of scientific expert opinion, the trial judge must assess 'whether the reasoning or methodology underlying the opinion is scientifically valid and … whether that reasoning or methodology properly can be applied to the facts in issue.'" *United States v. Frazier*, 387 F.3d 1244, 1262 (11th Cir. 2004) (quoting *Daubert*, 509 U.S. at 592-93). *Daubert* identified a non-exhaustive list of factors that may be helpful in assessing reliability: (1) whether a theory or technique can be or has been tested, (2) whether the theory has been peer-reviewed and published, (3) whether a technique has a known or potential rate of

error, and (4) general acceptance in the relevant scientific community. *Daubert*, 509 U.S. at 593-94. However, the reliability inquiry "is a flexible one," and the *Daubert* factors do not apply in every case. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141, 150 (1999) (quoting *Daubert*, 509 U.S. at 594).

The focus of the *Daubert* analysis "must be solely on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 595. "Thus, the proponent of the testimony does not have the burden of proving that it is scientifically correct, but that by a preponderance of the evidence, it is reliable." *Allison*, 184 F.3d at 1312. "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596. Under *Daubert*, "the rejection of expert testimony is the exception rather than the rule." *Moore*, 995 F.3d at 850 (quoting Fed. R. Evid. 702 Advisory Committee's Note to 2000 Amendments).

Rule 702's requirement that the expert testimony assist the trier of fact is satisfied if the testimony "concerns matters that are beyond the understanding of the average lay person." *Frazier*, 387 F.3d at 1262.

B. General causation versus specific causation.

The first reason Plaintiffs' experts did not need to identify a threshold dose is that general causation only concerns whether an agent can be harmful. Reference

Manual at 554 (general causation is "whether an agent is capable of causing disease"); *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1303 (11th Cir. 2014) (general causation is "whether the [substance] *can* cause the harm the plaintiff alleges") (citation omitted).

How much of an agent is sufficient to cause harm is a different question, which relates to *specific* causation—i.e., whether "the substance caused the plaintiff's *specific* injury." *Chapman*, 766 F.3d at 1303 (citation omitted). Knowledge of a threshold dose is often necessary to prove that a plaintiff was exposed to enough of the substance to cause that plaintiff's illness. *Williams v. Mosaic Fertilizer, LLC*, 889 F.3d 1239, 1245 n.2 (11th Cir. 2018); *McClain v. Metabolife Int'l, Inc*., 401 F.3d 1233, 1242 (11th Cir. 2005). But it is not necessary to establish general causation. *In re Chantix (Varenicline) Prod. Liab. Litig*., 889 F. Supp. 2d 1272, 1303 (N.D. Ala. 2012) (experts' general causation opinions would not be excluded based on their inability to identify how much Chantix causes adverse effects, which related to specific causation).

In the proceedings below, BP argued that a general causation opinion must provide a threshold dose to be helpful to the trier of fact in determining specific causation. But when litigation is bifurcated between general and specific causation, as it was here, there is no reason to require the threshold dose determination to be

made during the general causation phase, when it is neither necessary nor relevant, rather than deferring it to the specific causation phase, when it *is* relevant.

C. Epidemiological methodology.

The purpose of *Daubert*'s gatekeeping requirement is to "make certain that an expert … employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 152. Here, the relevant field is epidemiology, which "is generally considered to be the best evidence of causation in toxic tort actions." *Rider v. Sandoz Pharms. Corp*., 295 F.3d 1194, 1198 (11th Cir. 2002). Dr. Freeman and Dr. Solomon both have extensive expertise in epidemiology. Doc.469-1 at 3; Doc.466-1 at 3-6. And both followed what this Court has called the "epidemiological evidence" methodology. *Chapman*, 766 F.3d at 1308.

That methodology entails (1) reviewing epidemiological evidence to determine whether it shows an association between the agent and the disease under investigation, and (2) considering the Bradford Hill guidelines (or similar criteria) to assess whether the association is a cause-effect relationship. Reference Manual at 597-600; Restatement (Third) of Torts: Phys. & Emot. Harm §28(a) (2010), cmt. c.(3) ("Restatement"); Hill, *supra*.

No step of this methodology requires knowledge of a threshold dose. The epidemiology chapter of the Reference Manual (pp. 549-632) mentions threshold

dose several times, but never suggests that a threshold dose must be identified or considered to infer general causation from epidemiological evidence.[6] Neither does Sir Hill's seminal article. Hill, *supra*.

Some courts (including the district court, Doc.591 at 8) have confused threshold dose with the Bradford Hill guideline of "dose-response relationship," which Sir Hill called "biological gradient." Hill, *supra* at 298. They are two different concepts. A dose-response relationship is "[a] relationship in which a change in amount, intensity, or duration of exposure to an agent is associated with a change—either an increase or decrease—in risk of disease." Reference Manual at 622; *see also McClain*, 401 F.3d at 1241-42. It is not the same thing as a threshold dose, and the "biological gradient" Bradford Hill guideline does not require a threshold dose to be identified. Reference Manual at 603; Hill, *supra* at 298; Doc.514-3 at 5, ¶16. Even a dose-response relationship, correctly understood, is not essential for general causation. Reference Manual at 603 ("Thus, a dose-response relationship is strong, but not essential, evidence that the relationship between an agent and disease is causal."); Doc.514-3 at 5, ¶16. Therefore, a threshold dose cannot be essential either.

[6] However, threshold dose should be considered when attempting to infer human causation from animal studies, which are *toxicological* studies, not epidemiological. Reference Manual at 563.

D. Prior decisions.

District court decisions (including the one under review) have construed *McClain* as requiring threshold dose evidence to reliably show general causation. However, the relevant passages of *McClain* all concerned toxicological principles or specific causation, so they don't apply to the *epidemiological* methodology for establishing *general* causation.

In *McClain*, both general and specific causation were at issue. 401 F.3d at 1239-40, 1244, 1252. Two sentences in *McClain* have been construed as requiring evidence of a threshold dose, but both pertain to specific causation: (1) "In toxic tort cases, scientific knowledge of the harmful level of exposure to a chemical plus knowledge that plaintiff was exposed to such quantities are minimal facts necessary to sustain the plaintiff's burden," and (2) "A plaintiff must demonstrate the levels of exposure that are hazardous to human beings generally as well as the plaintiff's actual level of exposure to the defendant's toxic substance before he or she may recover." *McClain*, 401 F.3d at 1241 (cleaned up). The two requirements described in these sentences—threshold dose and sufficient exposure—are only necessary to prove specific causation.

Another *McClain* passage that has been misconstrued concerns the *toxicological* view of dose and response. Unlike epidemiology, toxicology focuses on identifying threshold doses. Reference Manual at 637 ("The science of toxicology

attempts to determine at what doses foreign agents produce their effects."). With that distinction in mind, here is the misconstrued passage:

> In his article Eaton describes some key principles of **toxicology** that a court should consider in "any attempt to establish whether a chemical exposure was causally related to a specific adverse effect or disease in an individual." *Id*. at 9. Foremost among these principles is the dose-response relationship.
>
> Dr. Eaton explains that "the relationship between dose and effect (dose-response relationship) is the hallmark of basic **toxicology**." *Id*. at 15. "Dose is the single most important factor to consider in evaluating whether an alleged exposure caused a specific adverse effect." *Id*. at 11. … Furthermore, "for most types of dose-response relationships following chronic (repeated) exposure, thresholds exist, such that there is some dose below which even repeated, long-term exposure would not cause an effect in any individual." *Id*. at 16.

401 F.3d at 1242 (quoting David Eaton, *Scientific Judgment and Toxic Torts—A Primer in Toxicology for Judges and Lawyers*, 12 J.L. & Pol'y 5, 9, 15-16 (2003)) (boldface and underlining added). This passage is inapplicable for two reasons. **First**, the underlined language shows that Dr. Eaton was discussing *specific* causation. And **second**, the last sentence (which explains threshold dose) is a principle of *toxicology*, not epidemiology. The epidemiological definition of "dose-response relationship" does not include threshold dose.

McClain is also distinguishable in that the experts in *McClain* did not apply the epidemiological methodology, had no expertise in epidemiology, and offered no epidemiological data to support their opinions. 401 F.3d at 1239, 1251-52. *McClain* assessed their testimony under "essential principles of toxicology" and four criteria

set forth in Dr. Eaton's toxicology-based article. *Id.* at 1242-43, 1251, 1255. Also, the experts' failure to identify a threshold dose only defeated the second Eaton criterion, sufficient exposure, which "focuses on the issue of individual causation." *Id.* at 1242-43. Thus, *McClain* does not require a *general* causation opinion to include a threshold dose, especially when the expert is applying an *epidemiology*-based methodology.

District courts have also construed *Chapman* as imposing a per-se requirement to identify a threshold dose. But like *McClain*, *Chapman* is distinguishable because the general causation experts in that case did not apply the "epidemiological evidence" methodology. 766 F.3d at 1307.

Chapman only required evidence of a threshold dose to satisfy a different methodology, "dose response," which is one of the three "indispensable" or "primary" methodologies, along with "epidemiological evidence" and "background risk of disease." *Id.* at 1308. *Chapman* affirmed the exclusion of the plaintiffs' general causation experts because they did not satisfy any of these methodologies: they did not satisfy "dose response" because they did not know how much of the product at issue must be used to cause the plaintiffs' harm (threshold dose), nor "epidemiological evidence" because their opinions were unsupported by epidemiological evidence, nor "background risk" because they did not know the background risk of the plaintiffs' condition. *Id.* at 1307-08.

In this case, by contrast, Dr. Freeman and Dr. Solomon followed the epidemiological evidence methodology. Also, the epidemiological studies they cited accounted for "background risk" by comparing exposed individuals to unexposed individuals. Doc.514-3 at 6, ¶19. Because their opinions are supported by at least one and arguably two primary methodologies, they were not required to satisfy the third one, "dose response," by identifying a threshold dose. (Although *Chapman* called the primary methodologies "indispensable," this Court has never required causation experts to apply all three. *See Rider*, 295 F.3d at 1199 ("This Court has long held that epidemiology is not required to prove causation in a toxic tort case.").)

Because this Court has never held that an expert following the epidemiological evidence methodology must calculate or consider a threshold dose to render an admissible general causation opinion, and there is no scientific or legal basis for such a requirement, the district court abused its discretion in excluding Plaintiffs' experts based on their failure to identify a threshold dose. *See Moore*, 995 F.3d at 850 ("A district court abuses its discretion when it applies the wrong legal standard."); *Allison*, 184 F.3d at 1321 ("[A]n abuse of discretion occurs when under *Daubert* the admissibility bar is too high.").

II. THE DISTRICT COURT ERRED IN REJECTING PLAINTIFFS' EXPERTS' RELIANCE ON RUSIECKI (2022).

The first step of the epidemiology-based methodology is determining whether an *association* exists between the agent and disease at issue—in other words,

whether persons exposed to the agent contract the disease more often than one would expect by chance. Reference Manual at 554.

The Rusiecki (2022) study shows just such an association—specifically, that that DWH responders who inhaled crude oil vapors have a significantly increased risk of chronic sinusitis. Doc.543-1 at 1, 7. Drs. Freeman and Solomon relied upon this study (among others) to support their general causation opinions, and it is arguably the strongest evidence they considered.

The district court rejected Dr. Freeman's and Dr. Solomon's reliance on Rusiecki (2022) by finding that they ignored or failed to adequately address "clear limitations" in the study. Doc.570 at 29-31, 58-60; Doc.591 at 6. That is incorrect. Drs. Freeman and Solomon addressed all the purported limitations of the study, including several that they explained were not actually limitations.

A. Study design.

Rusiecki (2022) is an analysis of data gathered in the Deepwater Horizon Oil Spill Coast Guard Cohort study, which was designed to investigate long-term health effects of oil response work exposures. Doc.543-1 at 3; Doc.469-1 at 20. It is a prospective cohort study, which is the top or second-most reliable type of epidemiological evidence. Doc.543-1 at 2; Doc. 466-1 at 16; Doc.570 at 27; 469-3 at 28(104); Doc.514-3 at 3, ¶8; Doc.466-6 at 135. The cohort consisted of over 40,000 U.S. Coast Guard personnel who were on active duty during the DWH

response, including both members who responded to the oil spill (responders) and members who did not (non-responders). Doc.543-1 at 3; Doc.469-1 at 20.

Rusiecki (2022) analyzed (1) "medical encounter data" in the members' military records over a period beginning 2.5 years before the DWH spill and ending 5.5 years after the spill, and (2) information provided by responders in two surveys regarding their exposure to oil or dispersants, including the route of exposure (such as inhalation, ingestion, skin contact, submersion in oily water, or being in the vicinity of burning oil). Doc.543-1 at 3-4; Doc. 469-1 at 20; Doc. 466-1 at 16.

Rusiecki (2022) made several comparisons of subgroups such as responders vs. non-responders, responders who were exposed to crude oil by any route vs. those who weren't, and responders who were exposed to crude oil via inhalation vs. those who weren't. Doc.543-1 at 6-7; Doc.469-1 at 21. For each comparison, the study calculated a "hazard ratio"—which is equivalent to "relative risk"[7]—for each disease or symptom of interest. Doc.543-1 at 5-7; Doc.469-1 at 20-21. A relative risk ("RR") expresses how frequently exposed individuals contract a disease compared to unexposed individuals. Reference Manual at 566. A RR of 1.0 means the risk of disease is the same in both groups, while a RR above 1.0 means the risk is higher in

[7] The magistrate judge and counsel for both sides treated the two terms as equivalent. Doc.570 at 28; Doc.619 at 267, 347-48.

exposed individuals—so "there is a positive association between the exposure to the agent and the disease, which could be causal." *Id.* at 567.

Rusiecki (2022) also calculated a confidence interval ("CI") for each RR. Doc.543-1 at 4. A CI expresses a likely range of RRs. Reference Manual at 580; Doc.469-3 at 23(84). If the range straddles 1.0, the result is not statistically significant, which means it could have resulted from random error; whereas if the entire range is above 1.0, the result *is* statistically significant, so there is an association that is unlikely to have resulted from random error. Reference Manual at 573, 575; Doc.469-3 at 24(86-87), 106(315); Doc.466-3 at 136-37.

A well-designed study should control for confounders—i.e., other risk factors. Reference Manual at 595-96. Accordingly, the RRs in Rusiecki (2022) were adjusted for age and sex in all comparisons, and for smoking status in all comparisons except responders vs. non-responders. Doc.543-1 at 4. As a further check against confounders, the authors performed several "sensitivity analyses" by repeating some comparisons restricted to certain subsets of the comparison groups. Doc.543-1 at 4; Doc.469-1 at 21; *see* Reference Manual at 593-95 ("Conducting a sensitivity analysis entails repeating the analysis using different assumptions … to see if the results are sensitive to the varying assumptions.").

B. Results.

The comparisons of some of the subgroups mostly produced non-significant results. Doc.543-1 at 5-6. However, a comparison of responders who were ever exposed to oil via inhalation vs. those who never had that exposure showed statistically significant increased risks for chronic sinusitis (RR 1.48, CI 1.06-2.06) and unspecified chronic sinusitis (RR 1.55, CI 1.08-2.22). Doc.543-1 at 7. This means responders who inhaled crude oil vapors showed a 48% increased risk of chronic sinusitis and a 55% increased risk of unspecified chronic sinusitis. Doc.469-1 at 21; Doc.466-3 at 164-65. These results were controlled for smoking status. Doc.543-1 at 7; Doc.556-1 at 4-5, ¶¶13, 16. Nonetheless, the authors ran a sensitivity analysis which confirmed that the results were not influenced by smoking. Doc.543-1 at 23; Doc.469-3 at 92(260); Doc.512-1 at 11; Doc.556-1 at 5, ¶14.

C. Dr. Freeman's and Dr. Solomon's analysis of the study.

Drs. Freeman and Solomon relied on Rusiecki (2022)'s oil inhalation findings to support their general causation opinions. Doc.469-1 at 20-22; Doc.466-1 at 16-17. Their reports discussed some of the study's strengths (such as the use of objective medical data, a large cohort, and the use of sensitivity analyses to address potential biases) and limitations (such as the reliance on self-reported exposure data and a possible "healthy worker effect."). Doc.469-1 at 20-21; Doc.466-1 at 16-17. Drs. Freeman and Solomon further discussed the study's strengths and limitations in their

depositions and declarations—as well as issues raised by BP that they did *not* consider to be limitations, as discussed below.

D. The R&R's erroneous rejection of Rusiecki (2022) based on purported internal inconsistencies.

The R&R's main reason for rejecting Rusiecki (2022) is it believed there were inconsistencies in the study's findings that Dr. Freeman and Dr. Solomon ignored or failed to address. Doc.570 at 28-29, 58-59. But in fact, both experts addressed the supposed inconsistencies and explained why they did not contradict or undermine the study's significant findings.

Non-significant results of other comparisons. The main inconsistencies found by the R&R are that the study found no statistically significant, increased risk of chronic sinusitis in its comparisons of (1) all responders vs. all non-responders, (2) responders who were exposed to crude oil by any route vs. those who weren't, and (3) responders who were ever in the vicinity of in-situ oil burns vs. those who weren't, but it *did* find such an increased risk in responders who were exposed to oil via inhalation vs. those who weren't. Doc.570 at 28-29. The R&R also states that the study found a *reduced* risk of chronic sinusitis among responders who were exposed to both crude oil and dispersants via any route, but fails to mention that this finding was statistically insignificant. Doc.570 at 29; Doc.543-1 at 9.

Drs. Freeman and Solomon explained why these comparisons of other subgroups did not contradict the findings of the oil inhalation comparison. Dr.

Freeman testified that inhalation of crude oil is the most relevant and sensitive measure of exposure because it is the exposure that will most affect the nose and sinuses, whereas the exposure measures used in the other comparisons (like being a responder, being exposed to oil by any means, or being in the vicinity of crude oil) are the *least* sensitive. Doc.469-3 at 88-91(244-47, 250, 253-54); Doc. 512 at 11. Therefore, the analyses of other subgroups did not invalidate the findings in the oil inhalation analysis. *Id.* at 91(253-54). The R&R rejects this explanation because it "shows the significance of Dr. Freeman's failure to identify a harmful level of exposure…." Doc.570 at 59. But the threshold dose issue is irrelevant to whether Dr. Freeman's explanation is valid.

Dr. Solomon similarly testified that the analyses of different subgroups should be expected to yield different findings showing different degrees of risk. Doc.466-3 at 31-32, 175-76; *see also* Hill, *supra* at 296-97 ("[D]ifferent results of a different inquiry certainly cannot be held to refute the original evidence….").

The Rusiecki (2022) authors gave the same explanation:

> As our exposure metrics progressed from less specific (i.e., responder vs. non-responder) to more specific in relevance to the respiratory tract (i.e., inhalation of crude oil vapors), we observed a general increase in number of respiratory conditions with elevated aHRs, as well as higher magnitude aHRs. In some cases (e.g., sinusitis) we observed a shift from having a null association to increased risk.

Doc.543-1 at 8.

These explanations make sense considering how the other subgroups were defined. The responder vs. non-responder analysis included *all* responders, including many who were never exposed to oil via any route. It also included all responders who were exposed to oil via routes that have no connection to the respiratory system, such as touching tar balls or wading in oily water. Dr. Solomon testified that she would not expect to see different rates of disease in such a comparison, which the Rusiecki authors described as "a crude exposure metric." Doc.466-3 at 161-62, 176; Doc.556-1 at 7; Doc.543-1 at 10. The authors also wrote that the responder vs. non-responder comparison could have been influenced by a "healthy worker effect," which "may have resulted in underestimating some of the risks." Doc.543-1 at 10-11. Dr. Solomon and Dr. Freeman made the same point. Doc.466-1 at 16-17; Doc.512-1 at 10-11.

The comparisons of responders who ever / never were exposed to oil, or to oil plus dispersants, included all responders who were exposed to oil by any means—including exposures that could not plausibly affect the sinuses, such as dermal contact, submersion, and ingestion. Doc.543-1 at 4, 6. As Dr. Freeman explained, it is not only "biologically sound" but "common sense … that the nose and sinuses would be most impacted by inhalation of crude oil vapors." Doc.512-1 at 11. The study authors likewise described "inhalation of crude oil vapors" as the "exposure more likely to directly affect the respiratory system." Doc.543-1 at 10.

These other comparisons also included all responders who were ever in the vicinity of burning oil. Doc.543-1 at 4, §2.4. But being in the vicinity of burning oil does not necessarily mean a responder inhaled any fumes from it. Dr. Freeman testified, "I'm not saying if you walk by crude oil, you're going to get … chronic sinusitis." *Id*. at 89(247). Dr. Solomon identified two more reasons why the vicinity-of-burning-oil comparison does not undermine her causation opinion. First, the sample size was very small, in that only 13 people in the "ever" category had chronic sinusitis and only 17 had unspecified chronic sinusitis. Doc.466-3 at 170-72; Doc.543-1 at 25. With such a small sample, a difference of just one case could "completely change the numbers."[8] Doc.466-3 at 171-72. Second, it is illogical that being near burning oil could *reduce* the risk of those diseases, as implied by the below-1.0 RRs listed in this comparison. *Id*.

Rhinitis. The R&R states, "Interestingly, the study also found … a reduced risk for chronic rhinitis for those who were exposed to oil versus those who weren't." Doc.570 at 29. Plaintiffs' experts addressed this supposed inconsistency. For starters, the results for chronic rhinitis were statistically insignificant. Doc.469-3 at 91-92(256-57); Doc.466-3 at 151-52. Dr. Freeman also testified that it is biologically implausible that inhaling crude oil could improve one's health, so the insignificant finding for chronic rhinitis is "better explained by just random scatter and small

[8] The CIs for these results show they are statistically insignificant. Doc.543-1 at 25.

numbers." Doc.469-3 at 91-92(256-57). He further testified that the different results for chronic rhinitis and chronic sinusitis are explained by the distribution of the two conditions and by doctors' personal idiosyncrasies in choosing a diagnosis when the conditions occur together. Doc.496-3 at 91(255-56). Dr. Solomon similarly testified that rhinitis is much less severe and "a bit more subjective as [an] outcome than chronic sinusitis." Doc.466-3 at 147.

The R&R criticizes another explanation Dr. Solomon gave, which was that chronic rhinitis frequently occurs without chronic sinusitis, while the converse is not true. Doc.570 at 29, n.20. However, Dr. Solomon gave a different explanation after she recalled that Rusiecki (2022) split rhinitis into two conditions, chronic rhinitis and allergic rhinitis, and only small numbers of responders were diagnosed with chronic rhinitis while far more were diagnosed with allergic rhinitis. Doc.466-3 at 149-50. Therefore, the insignificant results for chronic rhinitis are explained by small sample sizes, while the results for allergic rhinitis were probably insignificant because allergic rhinitis is not strongly associated with oil exposure. Doc.466-3 at 149-52. The R&R ignored this explanation.

Smoking sensitivity analysis. The R&R's last finding of inconsistency reflects fundamental misunderstandings of sensitivity analyses and statistical significance. The supposed inconsistency is that the oil-inhalation comparison's findings were no

longer statistically significant after "the study was restricted to 'never' smokers" or "adjusted to exclude ever smokers." Doc.570 at 29, 31.

In fact, the study was not "restricted" or "adjusted" in either manner. Rather, a sensitivity analysis was performed by repeating some of the comparisons after excluding ever-smokers, to check whether the findings of the main analyses were affected by smoking. This was explained in Dr. Freeman's declaration, his deposition, Dr. Solomon's supplemental declaration, and the study itself. Doc.512-1 at 10; Doc.469-3 at 92(260); Doc.556-1 at 5; Doc.543-1 at 4, 11. The R&R's mischaracterization of the sensitivity analysis is an abuse of discretion. *Carrizosa v. Chiquita Brands Int'l, Inc*., 47 F.4th 1278, 1320 (11th Cir. 2022) (district court abuses its discretion by mischaracterizing evidence relied upon by expert).

Drs. Freeman and Solomon also explained why the sensitivity analysis did not contradict, but *strengthened*, the findings of the main oil-inhalation analysis: the RRs in both analyses are very similar for chronic sinusitis (1.31 versus 1.48) and nearly identical for unspecified chronic sinusitis (1.54 versus 1.55). Doc.469-3 at 92(260); Doc.512-1 at 11; Doc.466-3 at 167-69; Doc.543-1 at 7, 23. Thus, the sensitivity analysis confirmed that the significant findings of the main oil-inhalation analysis were not confounded by smoking. Doc.512-1 at 11; Doc.466-3 at 168-69.

Drs. Freeman and Solomon further explained that the only reason statistical significance was lost in the sensitivity analysis is that eliminating all ever-smokers

reduced the sample size by nearly half, which reduced statistical power. Doc.469-3 at 92(259-60); Doc.466-3 at 169, 172-74; Doc.512-1 at 10-11; Doc.556-1 at 5; *see* Reference Manual at 573 (statistical insignificance can result from a small sample size). Therefore, the significant results of the main analysis were not weakened by the insignificant results of the sensitivity analysis, given that their RRs were nearly the same. Doc.466-3 at 172-73; Doc.512-1 at 11; Doc.566-1 at 5.

An article by two leading epidemiology authorities confirms this explanation:

> It is sometimes claimed that a literature or set of results is inconsistent simply because some results are "statistically significant" and some are not. This sort of evaluation is completely fallacious …: The results (effect estimates) from the studies could all be identical even if many were significant and many were not, the difference in significance arising solely because of differences in the standard errors or sizes of the studies.

Kenneth J. Rothman and Sander Greenland, *Causation and Causal Inference in Epidemiology*, 95 Am. J. Pub. Health S144, 148 (2005).

The R&R acknowledges that Dr. Solomon gave this explanation, but never addresses whether it is reasonable. Doc.570 at 31. Instead, it accuses Dr. Solomon of a "wholesale failure to discuss these clear limitations in the Rusiecki study," which is plainly incorrect. *Id*.; *see Seamon*, 813 F.3d at 987 (a district court abuses its discretion if it "makes findings of fact that are clearly erroneous"). The R&R also ignores that Dr. Freeman gave the same explanation.

E. Additional erroneous findings concerning Rusiecki (2022).

The R&R gives three more erroneous reasons for rejecting Dr. Freeman's and Dr. Solomon's reliance on Rusiecki (2022).

First, it finds that Dr. Solomon "did not discuss the fact that the study included self-reported exposure…." Doc.570 at 30. That is incorrect. Dr. Solomon's report notes that the exposure histories were based on survey responses, which means they were self-reported. Doc.466-1 at 16. It then addresses the main shortcoming of self-reported data, which is that it can introduce "recall bias." Reference Manual at 585; Doc.466-3 at 63. Dr. Solomon's report concludes that the exposure histories "would not suffer from recall bias" because they "were detailed and collected soon after deployment …." Doc.466-1 at 16. In her deposition, Dr. Solomon clarified that the exposure histories would be *much less likely* to suffer from recall bias for that reason. Doc.466-3 at 157-58. The Rusiecki (2022) authors made the same point: "[S]elf-reported exposure could have been influenced by recall bias, however, the median time between end of deployment to the response and completion of the exit surveys was relatively short …." Doc.543-1 at 10.

Also, self-reported exposure data is no reason to disregard an entire study. "[I]n most cases, objections to the inadequacies of a study are more appropriately considered an objection going to the weight of the evidence rather than its admissibility." *Rosenfeld v. Oceania Cruises, Inc*., 654 F.3d 1190, 1193 (11th Cir.

2011) (citation omitted). All studies have limitations (Reference Manual at 553), and most epidemiological studies rely on recall. Doc.466-3 at 63. The expert should consider whether and to what extent a limitation may compromise a study's findings, which Dr. Solomon did. Reference Manual at 553.

Second, the R&R finds that Dr. Freeman's general causation opinion was not limited to Rusiecki (2022) findings regarding inhalation of crude oil fumes, because the conclusion of his report finds there is a causal relationship between exposure to "chemicals associated [with] the [DWH] oil spill" and chronic sinusitis. Doc.570 at 59. This finding overlooks that the next sentence in Dr. Freeman's report is based on Rusiecki (2022): "Based upon the adjusted hazard ratio for chronic sinusitis associated with crude oil inhalation, there is a minimum additional 55% risk attributable to the exposure…." Doc.469-1 at 24; Doc.469-3 at 107(317). Also, Dr. Freeman considered other evidence showing an association between exposure to dispersants and sinus or nasal problems, which supports his broader reference to "chemicals associated with" the DWH spill. Doc.469-1 at 17, 19-20, 24.

Third, the R&R criticizes Dr. Freeman for not determining or considering whether the responders in Rusiecki (2022) "performed the same type of work as Plaintiffs or would have suffered comparable exposures." Doc.570 at 60. But that question is only relevant to *specific* causation. *McClain*, 401 F.3d at 1242 (whether an individual's exposure was sufficient to cause disease is an "issue of individual

causation."). Also, the purpose of the bellwether process is to determine general causation for BELO plaintiffs generally, not just those who performed the same work as Plaintiffs did.[9] BELO cases can be brought by plaintiffs who performed any kind of response work, onshore or offshore, and there is no evidence that the responders in Rusiecki (2022) only performed work that no BELO plaintiffs could have performed. Doc.45-1 at 9, 12(¶H), 14(¶Q), 28(¶OOOO).

Thus, the R&R's findings that Dr. Solomon and Dr. Freeman failed to discuss the "internal inconsistencies" and other "clear limitations" of Rusiecki (2022) are clearly erroneous. Doc.570 at 30-31, 59. Both experts explained their reasons for concluding that the study's limitations and supposed inconsistencies did not undermine their opinions. The R&R simply disagreed with some of their explanations and ignored the rest, thus substituting its own view of how to interpret and weigh the study. The district court's adoption of these rulings is an abuse of discretion. *Seamon*, 813 F.3d at 987 ("clearly erroneous" factual findings are an abuse of discretion); *Kuhn v. Wyeth, Inc*., 686 F.3d 618, 633 (8th Cir. 2012) ("[I]t is not the province of the court to choose between the competing theories when both are supported by reliable scientific evidence.").

III. THE DISTRICT COURT ERRONEOUSLY REQUIRED PLAINTIFFS' EXPERTS TO ANALYZE GENERAL CAUSATION

[9] Plaintiffs were selected as bellwethers under a scheme that sorted BELO plaintiffs by health condition and counsel, not job description or location. Docs.342, 348, 598.

FOR SPECIFIC CHEMICAL COMPONENTS OF CRUDE OIL AND DISPERSANTS.

The district court also excluded Plaintiffs' experts because their general causation analyses focused on crude oil and dispersants instead of specific chemicals within those substances. Doc.591 at 2, 9; Doc.570 at 3, 54. This was error because Plaintiffs were only required to show general causation for oil, dispersants, or other substances associated with the DWH spill, and no scientific or legal principle forbids an expert to determine general causation for such substances.

A. The correct framing of the causation issue.

The district court starts with this premise: "Plaintiffs must show through expert testimony that a chemical or mixture of chemicals from the oil spill caused their [medical conditions]." Doc.570 at 2. That is incorrect. Under the settlement agreement that governs BELO litigation, the causation issue is "Whether the [plaintiff's medical condition] was legally caused by his or her exposure to **oil**, other hydrocarbons, and other substances released from the [DWH spill] and/or **dispersants** and/or decontaminants used in connection with the RESPONSE ACTIVITIES[.]" Doc.45-1 at 69-70 (emphasis added). Nothing in the agreement requires a BELO plaintiff to prove that specific chemicals *within* these substances caused the plaintiff's medical condition.

Also, general causation is whether a "substance" or "agent" can cause an injury. *Chapman*, 766 F.3d at 1303, 1306 ("substance"); *McClain*, 401 F.3d at 1239

("agent"); Reference Manual at 554 ("agent"). The term "agent … refer[s] to any substance external to the human body that potentially causes disease or health effects." Reference Manual at 551, n.3. Crude oil and dispersants are "substances," so they are also "agents" and proper subjects for a general causation determination.

Thus, the district court's ruling that Plaintiffs may only show general causation for specific chemicals is factually and legally erroneous. *Seamon*, 813 F.3d at 987 (a district court abuses its discretion if it "applies an incorrect legal standard … or makes findings of fact that are clearly erroneous.").

B. Reliability.

Drs. Freeman and Solomon reliably analyzed general causation for crude oil and dispersants. As was discussed in Point II and will further be discussed in Points V and VI, they evaluated multiple peer-reviewed, published[10] studies of DWH response workers that examined the effects of exposure to crude oil or dispersants instead of the chemicals within those substances.

It is entirely proper for epidemiological studies to investigate associations between substances like crude oil or dispersants and adverse health effects, and no principle of epidemiology required Plaintiffs' experts to only consider studies of specific chemicals. The Reference Manual explains that "[e]pidemiological

[10] All the studies Dr. Solomon considered were published in peer-reviewed journals, and Dr. Freeman's report cited the same published DWH studies as hers did. Doc.466-5 at 133; Doc.556-1 at 4; Doc.469-1 at 18-20; Doc.466-1 at 15-16.

evidence identifies agents that are associated with an increased risk of disease," and an "agent" can be "any substance external to the human body." Reference Manual at 551 n.3, 552. As Dr. Freeman testified, "where there is an idiosyncratic environmental exposure which is maybe different for individuals, … it is not required that you know specifically exactly the chemical that they were exposed to that may have made them ill." Doc.469-3 at 26(93).

The R&R found it "problematic" that Dr. Freeman did not establish general causation for specific chemicals, because "not all workers had the same types of exposures and the available epidemiological studies do not all address the same exposure scenario." Doc.570 at 54. It further remarked that the crude oil "underwent weathering" and "changed its composition" as it traveled to shore, implying that onshore workers were only exposed to "weathered" oil that was less harmful than the fresher oil encountered by offshore workers. But again, those are issues of specific causation, not general. *McClain*, 401 F.3d at 1242 (whether an individual's exposure was sufficient to cause disease is an "issue of individual causation."). Also, there is no evidence that any of the studies Dr. Freeman and Dr. Solomon cited were limited to offshore workers, and BELO cases can be brought by both onshore and offshore workers. Doc.45-1 at 9, 12, 14.

Courts have found an expert's causation opinion regarding a substance or mixture to be reliable and admissible although the expert did not identify a specific

chemical constituent that caused injury. *E.g.*, *McCullock v. H.B. Fuller Co*., 61 F.3d 1038, 1043 (2d Cir. 1995) (expert's testimony that plaintiff could have been harmed by inhaling fumes from hot-melt glue was admissible although expert "did not know the chemical constituents" in the glue); *Clausen v. M/V NEW CARISSA*, 339 F.3d 1049, 1059-61 (9th Cir. 2003) (expert reliably concluded that exposure to oil was a possible cause of oyster deaths); *Maas v. BP Expl. & Prod., Inc*., 576 F. Supp. 3d 564, 568 (M.D. Tenn. 2021) (rejecting BP's argument that plaintiff's expert identified "no chemical" causing plaintiff's injuries and admitting expert's opinion that the injuries "were caused generally by Corexit" because "the law does not require more specificity than that").

IV. THE DISTRICT COURT ERRED IN EXCLUDING DR. FREEMAN'S GENERAL CAUSATION OPINION FOR CHRONIC SINUSITIS.

Dr. Freeman's general causation opinion is reliably supported by his application of the epidemiological evidence methodology. He evaluated epidemiological studies and data showing that DWH cleanup workers who were exposed to oil or dispersants have increased rates of chronic sinusitis or its precursor symptoms, applied the Bradford Hill guidelines to this evidence, and concluded that exposure to chemicals associated with the DWH spill generally causes chronic sinusitis. Doc.459-1 at 14-21.

The district court nonetheless excluded Dr. Freeman's opinion, finding that the studies he reviewed had essentially no value and his Bradford Hill analysis was

"cursory and superficial." Doc.570 at 55-61, 65; Doc.591 at 9. But the real basis for those findings is that the district court simply disagreed with Dr. Freeman's interpretation of the epidemiological evidence and his application of the Bradford Hill guidelines, which are matters of professional judgment. Restatement §28(a), cmt. c.(3). ("Whether an inference of causation based on an association is appropriate is a matter of informed judgment…."). Thus, the district court improperly reviewed the correctness of Dr. Freeman's conclusions rather than the reliability of his principles and methods. *Seamon*, 813 F.3d at 988 ("In assessing reliability, the court must focus 'solely on principles and methodology, not on the conclusions that they generate.'") (quoting *Daubert*, 509 U.S. at 595).

A. Epidemiological evidence.

As we discussed in Point II, one of the main studies that Dr. Freeman relied upon is Rusiecki (2022), which found that DWH responders who inhaled fumes from crude oil have a statistically significant increased risk of chronic sinusitis. Point II also discussed how Dr. Freeman reliably considered Rusiecki (2022) in his general causation analysis, and why the district court erred in finding otherwise.

Dr. Freeman also found support for his opinion in data gathered by the National Institute for Occupational Safety and Health (NIOSH) and a study called D'Andrea (2018). Doc.469-1 at 14-19, 22.[11] The R&R rejected these sources as

[11] Dr. Freeman's report also cited other studies that were given less emphasis.

essentially worthless because they have limitations and the NIOSH data concerns respiratory symptoms rather than chronic sinusitis. Doc.570 at 56-58, 60-61.

Preliminarily, the R&R's all-or-nothing approach misconceives the purpose for which Dr. Freeman cited these sources and is contrary to the methodology he followed. In his deposition, Dr. Freeman acknowledged that the NIOSH data and D'Andrea (2018) have limitations but made clear that neither of these sources was dispositive in forming his opinion—rather, they provide additional support for it. Doc.469-3 at 79(205-06, 208), 100(289), 102(300). He also explained why the "all-or-none" approach taken by the district court is incorrect: "It's not every study is either perfect, or every study is … terrible, and we don't pay attention to it. That's not the way you assess data or information when you're trying to assess a causal relationship." *Id.* at 42(158). His declaration further explained:

> While it may be inappropriate to use one study with multiple limitations and confounding factors alone to demonstrate causation, epidemiological methodology allows the use of the published study as a piece of evidence to evaluate overall causal relationships. …This approach allows for the evaluation of the totality of the evidence, rather than using a pick and choose approach….

Doc.512-1 at 4, ¶4.

Dr. Freeman is correct: an expert may reliably consider multiple sources of data that individually might be insufficient to support the expert's opinion. *Carrizosa v. Chiquita Brands Int'l, Inc.*, 47 F.4th 1278, 1320 (11th Cir. 2022) (reversing district court order that excluded expert opinion without considering "the full universe of

information" on which the expert relied, although the expert's sources of information would not have required reversal if considered individually); *Milward v. Acuity Specialty Prod. Grp., Inc*., 639 F.3d 11, 23 (1st Cir. 2011) ("The district court erred in reasoning that because no one line of evidence supported a reliable inference of causation, an inference of causation based on the totality of the evidence was unreliable."). As in *Carrizosa* and *Milward*, the district court erred in rejecting each individual source of epidemiological evidence as worthless instead of considering whether Dr. Freeman's opinion was reliably supported by the totality of the evidence.

NIOSH data. As part of a health hazard evaluation (HHE), NIOSH took a survey of onshore DWH cleanup workers asking whether they had been exposed to dripping oil, tar balls, dispersants, or dust; how frequently they were exposed; and whether they suffered any acute health symptoms. Doc.416-1 at 14-16. Dr. Freeman obtained the survey data and used it to calculate odds ratios (which are similar to RRs, *see* Reference Manual at 568) and CIs for each exposure. *Id.* at 16-17. Exposure to dripping oil, tar balls, dispersants, or dust resulted in statistically significant increases in reports of nose irritation, sinus problems, or sore throat. *Id.* at 17. The same was true when Dr. Freeman limited the analysis to sinus problems. *Id* at 17-18. His analysis also showed statistically significant dose-response relationships

between the frequency of exposure to dust or tar balls and these symptoms. *Id.*; Doc.469-3 at 102(298-99); Doc.512-1 at 6 ¶7(b).

The R&R found the NIOSH data to be "flawed in several respects," the first being that "the NIOSH HHE was a cross-sectional study." Doc.570 at 56. Dr. Freeman explained why this did not impair the data's value. The usual problem with cross-sectional studies is that they cannot show temporality, i.e., that the exposure preceded the disease. Reference Manual at 560-61; Doc.469-3 at 32(117-18). Dr. Freeman testified that with the NIOSH data, temporality is satisfied because it is known that the exposure preceded the symptoms. Doc.469-3 at 104(306-07). The R&R ignored this testimony.

The R&R also criticized the NIOSH data because it concerned acute symptoms rather than chronic conditions, and found that Dr. Freeman "fail[ed] to offer a reasonable explanation" for how the data "can be used to demonstrate an association between exposure and the development of chronic sinusitis…." Doc.570 at 56-57. However, Dr. Freeman never claimed that the NIOSH data *independently* shows that association. He testified, "It's only supporting information … not dispositive." Doc.469-3 at 102(300). Dr. Freeman also explained that chronic sinusitis always begins with symptoms such as nasal congestion and sinus problems, so studies that show a strong association between an exposure and those symptoms

are additional evidence of a plausible association with chronic sinusitis. Doc.469-3 at 84(226-28), 102(300); Doc.512-1 at 12-13, ¶12.

The R&R further found that the NIOSH data was "weakened" because it was based on self-reported data, which creates a potential for "recall bias" where persons with a disease recall past exposures more readily. Doc.570 at 58. Dr. Freeman addressed this limitation in his deposition. He explained that when studies rely on self-reported symptoms, there are ways to check for consistency within the data, such as when people who report being exposed more often also report the symptoms more often. Doc.469-3 at 30-31(110, 112-13). This is true of the NIOSH data: the workers with greater exposure were more likely to report symptoms, which they could not have manipulated through recall bias. *Id.* at 104(306).

Moreover, *all* studies have limitations; the question is whether Dr. Freeman considered whether and to what extent the limitations compromised the study's findings, which he did. Reference Manual at 553; *see also Rosenfeld*, 654 F.3d at 1193 (objections to inadequacies of a study generally go to the weight of the evidence). By finding that the NIOSH data could not reliably provide *any* support for Dr. Freeman's opinion, the magistrate judge improperly substituted her own interpretation and weighing of that evidence in place of Dr. Freeman's. Doc.570 at 58; *see In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs. & Prod. Litig.*, 509 F. Supp. 3d 116, 180 (D.N.J. 2020) ("[I]t is not the Court's position as

gatekeeper to determine whose interpretation of the studies is correct, as long as the competing interpretations are each rooted in some sound ground.").

The R&R also found that Dr. Freeman's consideration of the NIOSH data was undermined by his testimony that inhalation of oil fumes was the most sensitive measure of exposure used in Rusiecki (2022), because "the NIOSH survey asked only generally about the frequency of exposure and did not ask the 'more sensitive measure' about crude oil inhalation." Doc.570 at 59-60. However, the exposure classifications used in the studies (frequency of exposure and route of exposure) do not directly translate to each other, so the R&R had no basis to conclude that either study undermines the other.

D'Andrea (2018). D'Andrea (2018) evaluated the medical records of DWH cleanup workers at the time of their response work and seven years later. The study found that 40 out of 44 exposed workers, or 91%, had developed chronic sinusitis by the time of their seven-year follow-up, whereas none of them had that condition at their initial visit. Doc.469-1 at 18-19.

Dr. Freeman acknowledged that this study had limitations. His report noted that the sample size was limited because only 44 of the 117 workers returned for their seven-year follow-up evaluations. Doc.469-1 at 19. In his deposition, Dr. Freeman agreed that this could have influenced the study's statistics, but opined that "it doesn't mean the study is irretrievably flawed in some way." Doc.469-3 at 79-

80(208-09). Dr. Freeman also acknowledged that the study participants appeared to be personal injury plaintiffs who were referred by their attorneys. Doc.469-3 at 49(186-87). Although this introduced a potential bias, Dr. Freeman testified that it was mitigated because the participants' health conditions were confirmed with medical diagnoses, so there was no risk of overreporting their symptoms; they only could have reported being exposed when they were not. *Id.* at 49(187-88), 79(206-07).

Dr. Freeman concluded that D'Andrea (2018) is "certainly not a perfect study, but it's not a fatally flawed study where you have to reject everything that they said." Doc.469-3 at 79(205). The R&R contrarily found that the study "cannot be used as part of a reliable method for arriving at a general causation opinion," which again improperly substituted the magistrate judge's own interpretation of the study in place of Dr. Freeman's. Doc.570 at 61.

B. Bradford Hill analysis.

Dr. Freeman discusses the Bradford Hill guidelines in two sections of his report. The first section explains the guidelines generally and includes a definition of each one. Doc.469-1 at 9-12. The other section appears near the end of the report and explains how Dr. Freeman applied each guideline. *Id.* at 22-23.

The R&R initially finds that Dr. Freeman's "analysis of the Bradford Hill factors is cursory and superficial." Doc.570 at 65. However, Dr. Freeman's report

shows otherwise—it explains his application of each guideline in detail. Doc.456-1 at 22-23. Plus, the R&R's subsequent findings show that the magistrate judge simply disagreed with Dr. Freeman's application of three of the nine guidelines. This approach is not only contrary to *Daubert*, but at odds with the epidemiology-based methodology. The Reference Manual explains,

> There is no formula or algorithm that can be used to assess whether a causal relationship is appropriate based on these [Bradford Hill] guidelines. … Although the drawing of causal inferences is informed by scientific expertise, it is not a determination that is made by using an objective or algorithmic methodology.

Reference Manual at 600.

The R&R first criticizes Dr. Freeman's application of the "consistency" guideline, in which he found that the three studies discussed above "demonstrate consistent associations between exposure to products of the [DWH] oil spill and sinusitis or chronic sinusitis." Doc.459-1 at 22. The R&R disagreed because the NIOSH data concerned symptoms while the other two studies involved chronic sinusitis, and because Dr. Freeman relied on Rusiecki (2022)'s findings regarding oil inhalation "while the other two studies included additional exposure scenarios." Doc.570 at 65.

The R&R's focus on these distinctions misses the point, which is that all three studies show that exposures to products of the DWH spill are associated with chronic sinusitis and its symptoms. The R&R also misconceives the "consistency" guideline,

which Dr. Freeman explained thus: "The repetitive observation of a causal relationship *in different circumstances* strengthens the causal relationship. Evidence of consistency can come from multiple studies of *varied* populations." Doc.456-1 at 11 (emphasis added). Sir Hill gave a similar explanation: "Has it been repeatedly observed by different persons, in different places, circumstances, and times?" Hill, *supra* at 296.

The R&R next criticizes Dr. Freeman's finding under the "coherence" guideline as "cursory" because it states, "It certainly 'makes sense' that exposure to inhaled irritants can cause acute and chronic upper respiratory illnesses." Doc.570 at 66; Doc.469-1 at 23. Here, the R&R overlooks that the "coherence" guideline sets a low bar, which Dr. Freeman explained this way: "A causal conclusion should not fundamentally contradict present substantive knowledge—it should 'make sense' given current knowledge." Doc.469-1 at 12. Others have described it similarly: "*Coherence* has been viewed as being similar to *biological plausibility*, in that the cause-and-effect story should make sense with all knowledge available to the researcher…." Kristen M. Fedak et al., *Applying the Bradford Hill Criteria in the 21st Century: How Data Integration has Changed Causal Inference in Molecular Epidemiology*, 12 Emerging Themes Epidemiology 14 (2015), https://doi.org/10.1186/s12982-015-0037-4 (italics in original, underlining added).

Also, an earlier section of Dr. Freeman's report further explains why a causal association "makes sense": "It is not difficult to understand, from common experience, that an inhaled chemical irritant can cause inflammation of the nasal sinuses resulting in acute illness, and that in some cases, the acute illness can persist and become chronic." Doc.469-1 at 9. Another passage explains that studies have shown associations between respiratory irritants and chronic sinusitis, and such irritants are found in crude oil and dispersants. *Id.* at 13-14.

The R&R also criticizes Dr. Freeman's statement that "[t]he chain of causation between the acute and chronic symptoms in the populations studied over time is clearly established, and contiguous," because "his report offers no explanation for this claim." Doc.570 at 66. That statement, however, is a partial quote of Dr. Freeman's "temporality" analysis, which the R&R does not find to be cursory or unreliable (nor was it). Doc.469-1 at 23.

The R&R lastly criticizes Dr. Freeman's application of the "biological gradient" guideline because it relies on the dose-response relationship shown by his analysis of the NIOSH data, which concerned acute symptoms rather than chronic sinusitis. Doc.570 at 66; Doc.469-1 at 23. As explained previously, Dr. Freeman's analysis of the NIOSH data lends additional support to his general causation opinion, so the dose-response relationship shown by the data strengthens that support. Doc.469-3 at 104(306). But even if Dr. Freeman's "biological gradient" finding were

disregarded, a dose-response relationship is not essential for finding general causation. Reference Manual at 603; *see also* Hill, *supra* at 299 ("None of my nine viewpoints … can be required as a *sine qua non*.").

In sum, Dr. Freeman reliably analyzed the epidemiological evidence and Bradford Hill guidelines. The district court abused its discretion by improperly reviewing Dr. Freeman's conclusions rather than his methodology, misconstruing the evidence, and misunderstanding how the epidemiology-based methodology is applied. *Carrizosa*, 47 F.4th at 1296, 1320; *Seamon*, 813 F.3d at 987-88.

V. THE DISTRICT COURT ERRED IN EXCLUDING DR. SOLOMON'S GENERAL CAUSATION OPINION.

Dr. Solomon also reliably analyzed the relevant studies and considered the Bradford Hill guidelines. But as with Dr. Freeman, the district court excluded her opinion based on findings that are factually inaccurate, are contrary to the principles and methodology Dr. Solomon followed, and that improperly substitute its own conclusions in place of hers.

A. Dr. Solomon's methodology and analysis.

We have summarized Dr. Solomon's methodology as reviewing epidemiological studies and applying the Bradford Hill guidelines. However, she also evaluates other lines of evidence, including animal studies, *in vitro* studies, and other relevant scientific information. Doc.466-1 at 8-9, 13.

After explaining her methodology, Dr. Solomon's report discusses the anatomy and functioning of the respiratory tract. *Id.* at 9-10. The next section cites a multitude of non-DWH epidemiological studies, animal studies, *in vitro* studies, and other sources, all of which show that exposure to particulate matter or chemicals found in oil and dispersants can damage or disrupt the functioning of cells in the upper respiratory tract, which increases the risk of chronic sinusitis. *Id.* at 11-13. Next the report discusses experiments showing that chemicals in spilled crude oil and dispersants can become airborne in aerosolized particles of seawater and deposited in the upper respiratory tract. *Id.* at 14-15. The remaining sections discuss epidemiological studies and Dr. Solomon's Bradford Hill analysis. Dr. Solomon concludes that inhalation of aerosolized particles containing petroleum hydrocarbons and dispersants can cause chronic sinusitis. *Id.* at 3, ¶4.

B. Epidemiological studies.

The epidemiological study that Dr. Solomon mainly relied upon is Rusiecki (2022). Doc.466-1 at 16-17; Doc.466-3 at 24. As we discussed in Point II, Dr. Solomon reliably analyzed that study, and her general causation opinion is well supported by its finding of a statistically significant association between inhalation of crude oil fumes and chronic sinusitis.

Dr. Solomon also considered a study called McGowan (2017), which found that DWH workers exposed to dispersants had statistically significant increases in

burning of the nose, throat, and lungs. Doc.466-1 at 15, ¶36. The R&R criticizes this study because it is "based on self-reported symptoms, which can result in bias, over-reporting of symptoms, and exposure misclassification," and because it focused on acute rather than chronic conditions. Dr. Solomon addressed these issues in a deposition from another BELO case, which BP filed with its *Daubert* motion. She testified that McGowan (2017) was a large and well-designed cohort study, which compensated for its shortcomings, and the risk of exposure misclassification tends to bias a study toward a null finding or underestimating an exposure's true effect (which would favor BP). Doc.466-5 at 168-71. Although McGowan (2017) didn't ask about sinusitis, she still considered it "quite important in terms of other effects on the respiratory tract that are relevant." *Id.* at 169.

The R&R also comments that "the authors specifically stated the results '*do not allow exploration of exposure-response relationships*.'" Doc.570 at 26 (emphasis in original). That is immaterial because "exposure-response relationships" means *dose*-response relationships, and Dr. Solomon did not rely on this study as evidence of a dose-response relationship.

Dr. Solomon's declarations discuss another study, Lawrence (2022), which found that working on the DWH cleanup effort in any capacity was significantly associated with increased risks of asthma. Doc.514-3 at 4; Doc.556-1 at 7. It also found dose-response relationships between exposure to chemicals contained in crude

oil and asthma. Doc.514-3 at 4-5, ¶¶13, 16. Dr. Solomon found this study relevant because asthma and chronic sinusitis are both inflammatory diseases of the respiratory tract with similar biological mechanisms. Doc.514-3 at 4, ¶¶10-11; Doc. 556-1 at 7-8.

The R&R states that Dr. Solomon could not rely on Lawrence (2022) because it was released after her report and deposition. Doc.570 at 31. However, BP decided that Dr. Solomon *should* be able to address Lawrence (2022) because it was released after her report, which is why BP did not move to strike her first declaration. Doc.619 at 260-61. Also, BP filed a reply and declarations of its experts criticizing Lawrence (2022), so it was not prejudiced. Docs.543 at 12-14, 543-2 at 6-8, 543-3 at 3-4.

The R&R also claims that Dr. Solomon failed to discuss "several limitations" of Lawrence (2022) but mentions only two: the study was based on self-reported symptoms of wheezing and self-reported asthma, and the findings lost statistical significance when self-reports of wheezing were removed (failing to mention that this was a sensitivity analysis). Doc.570 at 32. This is another clearly erroneous finding—Dr. Solomon *did* address those criticisms in her supplemental declaration. Doc.556-1 at 7.

Dr. Solomon's report also mentions D'Andrea (2018) and two non-DWH studies, Velasquez (2020) and Dietz de Loos (2021), and describes several limitations of the latter two studies. Doc.466-1 at 15-16. The R&R criticizes Dr.

Solomon's report for failing to explain how these studies were relevant to her opinion or how their limitations affected it. Doc.570 at 26-27. But it is self-evident from her report that she gave them little or no weight.

C. Bradford Hill.

The R&R finds that Dr. Solomon "failed to meaningfully consider the Bradford Hill factors" because she addresses only three of them in the conclusion of her report. Doc.570 at 32-33. However, an earlier section of her report explains why she did so. Dr. Solomon correctly notes that the Bradford Hill guidelines "were never intended to be absolute, and an inference of a causal relationship does not require that all the factors be met." Doc.466-1 at 8; *see* Hill, *supra* at 299. Only the "temporality" guideline is essential, while several others are not always relevant. Doc.466-1 at 8. Dr. Solomon also explained that other frameworks for causal investigations have been developed, which all include an evaluation of the *quality*, *coherence*, and *temporality* of the evidence. *Id.* at 8-9. Therefore, Dr. Solomon's analysis focuses on those factors. She considers all the other Bradford Hill guidelines, but no single one of them would change her opinion if the three key factors are met. *Id.* at 9.

The conclusion of Dr. Solomon's report assesses those three factors. *Id.* at 18, ¶23. The R&R accuses her of addressing them in "summary fashion," but her report gives a sufficient and clear analysis of each one: the overall *quality of the evidence*

is "moderate" and combines multiple lines of evidence, including DWH studies showing a statistically-significant increased risk of chronic sinusitis; the evidence is *coherent*, in that multiple lines of evidence point to the same conclusion; and Rusiecki (2022) shows that *temporality* is satisfied. *Id.*

Contrary to the R&R's ruling, no principle of epidemiology or legal precedent requires Dr. Solomon to give equal weight to all the Bradford Hill guidelines or to set forth her analysis of all nine guidelines in her report. Dr. Solomon gave a reasoned explanation for focusing on three key factors, with citations to supporting scientific articles. Doc.466-1 at 8-9. Sir Hill did not regard all his guidelines as equally important; for example, he wrote that specificity should not be over-emphasized, plausibility "is a feature I am convinced we cannot demand," and experimental evidence is only "occasionally" available. Hill, *supra*, at 297-98. And this Court has never held that a causation expert must discuss or even consider all nine guidelines—in fact, it has never mentioned Bradford Hill.

Also, Dr. Solomon's report and declarations address other guidelines besides quality, coherence, and temporality. The sections of her report explaining how petroleum-related chemicals can damage the respiratory tract support the "plausibility" guideline. Doc.466-1 at 9-13; Doc.514-3 at 5, ¶14(b). And her declaration states that Lawrence (2022) supports the "consistency," "analogy," "plausibility," and "biological gradient" guidelines. Doc.514-3 at 4-5, ¶¶11, 16.

D. Dose-response and background risk.

The R&R finds that Dr. Solomon failed to discuss dose-response relationships or to consider the background risk of disease. Doc.570 at 33-35. That is incorrect. First, Dr. Solomon's declaration discusses the dose-response relationship found by Lawrence (2022). Doc.514-3 at 4, ¶13. Even if that study were disregarded, a dose-response relationship isn't essential evidence of causation. Reference Manual at 603.

Second, Dr. Solomon testified that the background risk for chronic sinusitis is 10-15% and she considered it in her analysis, although she didn't discuss it in her report. Doc.466-3 at 57. Dr. Solomon's declaration further explained that background risk is accounted for in studies such as Rusiecki (2022) and Lawrence (2022), which compare the risks of exposed and unexposed individuals. Doc.514-3 at 6, ¶19. The unexposed individuals face the background risk of the disease, so the studies' findings of significantly increased risks among exposed workers means their risk is higher than the background risk. *Id.* The R&R rejects this explanation, but it is entirely correct: when a study finds a RR above 1.0, "there is a positive association between exposure to the agent and the disease," which means they "occur together more frequently than one would expect by chance." Reference Manual at 566-67. Dr. Solomon's testimony is also supported by *McClain*, which explained that a reliable methodology could be supported by evidence showing that exposure to an agent "increases the risk" of a disease above the "usual incidence." 401 F.3d at 1244.

Dr. Solomon reliably analyzed the epidemiological evidence, along with other lines of evidence, and reliably applied the Bradford Hill guidelines. The district court's exclusion of her general causation opinion is based on findings that mischaracterize the evidence, impermissibly review the correctness of her conclusions, and misconceive the relevant scientific principles, and is an abuse of discretion. *Carrizosa*, 47 F.4th at 1296, 1320; *Seamon*, 813 F.3d at 987-89.

VI. THE DISTRICT COURT ERRED IN GRANTING SUMMARY JUDGMENT AGAINST PLAINTIFFS JENKINS AND SIPLES.

The district court granted BP's motion for summary judgment because it had excluded all of Plaintiffs' general causation experts. Doc.570 at 77-78; Doc.591 at 10. Because the district court should have admitted Dr. Freeman's and Dr. Solomon's general causation opinions regarding chronic sinusitis, it erred in granting summary judgment against Mr. Jenkins and Mr. Siples.

CONCLUSION

Because the district court abused its discretion in excluding Dr. Freeman's and Dr. Solomon's testimony regarding general causation of chronic sinusitis, the Court should reverse the district court's order excluding that testimony and granting summary judgment against Mr. Jenkins and Mr. Siples, as well as the final judgments entered against them.

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g), the undersigned hereby certifies that this brief complies with the word limit of Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure. According to the word-processing system used to prepare the brief, excluding sections exempted by Fed. R. App. P. 32(f) and 11th Cir. R. 32-4, the brief contains a total of 12,999 words.

This brief complies with the typeface and type-style requirements of Fed. R. App. P. 32(a)(5) and 32(a)(6) because it has been prepared using a proportionally-spaced typeface in 14-point font.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on **September 15, 2023**, I electronically filed the foregoing with the Clerk of the District Court by using the CM/ECF system which will send a notice of electronic filing to George Hicks (george.hicks@kirkland.com) and Aaron Nielson (aaron.nielson@kirkland.com), Kirkland & Ellis LLP, 1301 Pennsylvania Ave. NW, Washington, DC 20004; and Francis M. McDonald, Jr. (fmcdonald@mtwlegal.com) and Sarah A. Long (slong@mtwlegal.com), McDonald Toole Wiggins, P.A., 111 N. Magnolia Avenue, Suite 1200, Orlando, FL

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